

may immediately file another exception request. Any subsequent exception request must address and document the issues cited in CMS' denial letter.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005]

§413.182 Criteria for approval of exception requests.

(a) CMS may approve exceptions to a pediatric ESRD facility's prospective payment rate if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002.

(b) The pediatric ESRD facility must demonstrate, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(1) Pediatric patient mix, as specified in §413.184.

(2) Self-dialysis training costs in pediatric facilities, as specified in §413.186.

[70 FR 70331, Nov. 21, 2005]

§413.184 Payment exception: Atypical service intensity (patient mix).

(a) *Qualifications.* To qualify for an exception to its prospective payment rate based on its pediatric patient mix a facility must demonstrate that—

(1) At least 50 percent of its patients are individuals under 18 years of age;

(2) Its nursing personnel costs are allocated properly between each mode of care;

(3) The additional nursing hours per treatment are not the result of an excess number of employees;

(4) Its pediatric patients require a significantly higher staff-to-patient ratio than typical adult patients; and

(5) These services, procedures, or supplies and their per treatment costs are clearly prudent and reasonable when compared to those of pediatric facilities with a similar patient mix.

(b) *Documentation.* (1) A pediatric ESRD facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed and filed cost report (in accordance with cost re-

porting requirements under §413.198) showing—

(i) Age of patients and percentage of patients under the age of 18;

(ii) Individual patient diagnosis;

(iii) Home patients and ages;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Diabetic patients; and

(vi) Patients isolated because of contagious disease.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

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§413.186 Payment exception: Self-dialysis training costs in pediatric facilities.

(a) *Qualification.* To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the pediatric ESRD facility must establish that it incurs per treatment costs for furnishing self-dialysis and

home dialysis training that exceed the facility's payment rate for the training sessions.

(b) *Justification.* To justify its exception request, a facility must—

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

(c) *Criteria for determining proper cost reporting.* CMS considers the pediatric ESRD facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality.

(d) *Limitation of exception requests.* Exception requests for a higher training rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

(e) *Documentation.* The pediatric ESRD facility must provide the following information to support its exception request:

(1) A copy of the facility's training program.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients.

(5) Number of patients trained for the current year and the prior 2 years on a monthly basis.

(6) Projection for the next 12 months of future training candidates.

(7) The number and qualifications of staff at training sessions.

(f) *Accelerated training exception.* (1) A pediatric ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (normally 3 times a week for hemodialysis). Continuous cycling peritoneal dialysis (CCPD) and contin-

uous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities; ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided.

(2) If a pediatric ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the—

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility receives in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

(3) An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training.

(4) In computing the payment amount under an accelerated training exception, CMS uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(5) To justify an accelerated training exception request, an ESRD facility must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period.

(6) The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's—

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

(7) The total treatments from the patient list must be the same as the total treatments reported on the cost report filed with the request.

[70 FR 70331, Nov. 21, 2005]